March 8, 2024

Boston Scientific Corporation
Tijana Prodanovic
Sr. Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K234046
Trade/Device Name: WallFlex Colonic Stent System with Anchor Lock Delivery System;
WallFlex Duodenal Stent System with Anchor Lock Delivery System;
WallFlex Colonic Soft Stent System with Anchor Lock Delivery System;
WallFlex Duodenal Soft Stent System with Anchor Lock Delivery System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: MQR, MUM
Dated: February 9, 2024
Received: February 9, 2024

Dear Tijana Prodanovic:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anthony Lee -S

Anthony Lee, Ph.D.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234046

Device Name

WallFlex Colonic Stent System with Anchor Lock Delivery System WallFlex Duodenal Stent System with Anchor Lock Delivery System
WallFlex Colonic Soft Stent System with Anchor Lock Delivery System
WallFlex Duodenal Soft Stent System with Anchor Lock Delivery System

Indications for Use *(Describe)*

The WallFlex Colonic Stent System with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstructions prior to colectomy in patients with malignant strictures.

The WallFlex Duodenal Stent System with Anchor Lock Delivery System is indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms.

The WallFlex Colonic Soft Stent System with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstructions prior to colectomy in patients with malignant strictures.

The WallFlex Duodenal Soft System with Anchor Lock Delivery System is indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) #: K234046

510(k) Summary

Prepared on: 2024-02-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Boston Scientific Corporation
Applicant Address	300 Boston Scientific Way Marlborough MA 01752 United States
Applicant Contact Telephone	5083820440
Applicant Contact	Mrs. Tijana Prodanovic
Applicant Contact Email	tijana.prodanovic@bsci.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	WallFlex Colonic Stent System with Anchor Lock Delivery System WallFlex Duodenal Stent System with Anchor Lock Delivery System WallFlex Colonic Soft Stent System with Anchor Lock Delivery System WallFlex Duodenal Soft Stent System with Anchor Lock Delivery System
Common Name	Expandable, metallic colonic stent Expandable, metallic duodenal stent
Classification Name	Esophageal Prosthesis
Regulation Number	21 CFR 878.3610
Product Code(s)	MQR,MUM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201159	Wallflex Colonic Stent System with Anchor Lock Delivery System	MQR, MUM
K200257	WallFlex Colonic Soft Stent System with Anchor Lock Delivery Sy	MQR, MUM

Device Description Summary

21 CFR 807.92(a)(4)

The WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System each consist of two components: the implantable metal stent and the anchor lock delivery system.

The proposed stent is manufactured of Nitinol. The stent will be offered in two diameters, 22mm with a 27mm flare and 25mm with a 30mm flare. Each diameter will be available in three lengths, 6cm, 9cm, and 12cm. The WallFlex Duodenal Stent will only be offered in the 22mm/27mm stent diameter (all lengths) preloaded on the 230cm Anchor Lock Delivery System. The WallFlex Colonic Stent will be offered in the 22mm/27mm and 25mm/30mm diameters (all lengths) preloaded on the 230cm or 135cm Anchor Lock Delivery System. The Anchor Lock delivery system consists of a coaxial tubing assembly that constrains the stent on the delivery catheter shaft until the stent is released by retracting the exterior tube.

The WallFlex™ Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex™ Duodenal Soft Stent System with Anchor Lock Delivery System each consist of two components: the implantable metal stent and the Anchor Lock Delivery System.

The stent is manufactured from Nitinol wires braided together to form a cylinder with a flared end. The wires are looped at both stent ends and welded at the non-flared end. The WallFlex Colonic Soft Stent and the WallFlex Duodenal Soft Stent will be offered in three diameters: 22 mm with a 27 mm flare, 20 mm with a 25 mm flare, and 18 mm with a 23 mm flare. Each diameter will be available in three

lengths, 6cm, 9cm, and 12cm. The stent sizes that are shared between the WallFlex Colonic Soft Stent and the WallFlex Duodenal Soft Stent are identical in all aspects of their design; the only difference is in indication.

The stent is compressed on a flexible catheter for delivery. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. There are 3 radiopaque marker bands on the delivery system to facilitate placement; the exterior tube marker band, the deployment limit marker band, and the post deployment marker band. The exterior tube marker band is located adjacent to the leading end of the stent and the deployment limit marker band is located adjacent to the trailing end of the stent. The deployment limit marker band identifies the stent deployment limit, the point beyond which the stent cannot be reconstrained. The post deployment marker band, situated 4cm from the trailing end of the constrained stent, helps to facilitate accurate placement of the stent. The only design difference between the colonic and duodenal product offerings is how the stent is loaded onto the delivery system. The colonic stent is loaded with the flare is distal to the operator, and the duodenal stent is loaded with the flare is proximal to the operator.

The Anchor Lock stent holder is located at the trailing end of the stent and secures the stent on the delivery system to aid in reconstrainment when repositioning the stent. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in. / 0.89 mm guidewire. The device may be inserted through the working channel of a 9 French endoscope (minimum channel diameter 3.2mm scope). The WallFlex Colonic/Duodenal Soft Stent with Anchor Lock Delivery System will be offered in 230cm.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The WallFlex Colonic Stent System with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstructions prior to colectomy in patients with malignant strictures.

The WallFlex Duodenal Stent System with Anchor Lock Delivery System is indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms.

The WallFlex Colonic Soft Stent System with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstructions prior to colectomy in patients with malignant strictures.

The WallFlex Duodenal Soft System with Anchor Lock Delivery System is indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System, WallFlex Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex Duodenal Soft System with Anchor Lock Delivery System are identical to the predicate WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System (K201159), WallFlex Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex Duodenal Soft System with Anchor Lock Delivery System (K200257) respectively, in intended use, indications for use, classification, principles of operation, technical characteristics, performance, and materials.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System, WallFlex Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex Duodenal Soft System with Anchor Lock Delivery System are identical to the predicate WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System (K201159), WallFlex Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex Duodenal Soft System with Anchor Lock Delivery System (K200257) respectively, in intended use, indications for use, classification, principles of operation, technical characteristics, performance, and materials.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The proposed WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System, WallFlex Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex Duodenal Soft System with Anchor Lock Delivery System are compliant with the FDA's guidance document Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (issued on October 10, 2023). MR evaluation was conducted following ASTM F2503e2020: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance, and the resultant data supports the proposed updated labeling.